

PSJ17 Exh 50

I - 1, 2, 3

D - 1, 2, 3, 5, 14

RMP Meeting with RK 11/13/03

Background

RMP report was submitted on 10/1/03 to TS as a draft. I was asked by TS to wait to distribute the report until he could check with RK to make sure it was okay.

Later learned that report had been given to AC to act on. 11/3/03 confirmed with TS my understanding that I was NOT to distribute report yet. On 11/11/03, AC was in my office on another matter (upcoming Orsymonde audit trip) and I asked him when I would be allowed to distribute the draft RMP report. I reminded him that it was about 6 weeks since the draft was completed. He indicated that he was not aware that it was a draft.

Meeting

The morning of 11/13/03, AC called a meeting for 1:00 in his office to discuss the RMP audit report. The meeting was sent by AM to AC, TS and myself. At about 3 minutes to 1:00, the meeting time was changed to 2:00. At about 2 minutes to two I went in to TS's office to walk down together to AC's office. We got most of the way there and TS said he had the wrong file and had to go back. I waited with AC in AC's office. When TS returned, he had RK with him.

We began discussing the RMP report. I was instructed to not distribute the report but to call a meeting with those that had participated in the audit to verify that the draft was correct. I was to give the participants a copy at the meeting and I was to collect it afterwards. I was to label the report "CONFIDENTIAL - DO NOT COPY". We discussed the distribution of the final report at some length. There was apparently a concern that the report might "get into the wrong hands". I indicated that I did not think that the report should be kept a secret and that we could easily address the issues in the report by revising and filing the RMP to accurately reflect our current activities.

RK (who had actually slept through part of the discussion) turned in his chair to face me and appeared to be physically trembling. He said that in all his 24 years of experience in this business he had never, "I mean never" (he repeated for emphasis), encountered an auditor who had refused to reduce distribution of an audit report, had refused to control the copies and refused to mark it confidential. I interrupted him at that point to correct the misunderstanding that I had refused to mark the document confidential. I further indicated that I simply felt that the report needed to be in the hands of those it would take to rectify the situation, that being Cephalon's non-compliance with the filed RMP.

The distribution listed on the draft included the directors of Regulatory Affairs, Product Safety and Marketing. In the case of RA and PS, this was the management that the participant reported to. In the case of Marketing, the director was the participant because the responsible marketing position had recently (at the time of the audit) been vacated. In addition to those, the associate director of QA (my supervisor, TS) was on the distribution. I, of course, as the author was in the "from" field. The QA File was in the "To" field. No one else was on the list. I asked who it should be distributed to instead of those already listed. There was discussion of circulating it at the VP level. RK's contribution to the distribution was only to add, not to take away anyone.

RK then began to query me on the audit SOP that had been the subject of previous problems between us (last year's review). I reminded him that that SOP was not applicable to the RMP as it covered vendor qualification audits and this was an internal audit. I got the sense that the SOP queries were prompted by some dissatisfaction on RK's part with the vendor audit SOP. He nor TS had ever previously indicated to me that there was any problem with the vendor audit SOP which was published in July.

In the end it is my understanding that it was agreed that the distribution was just as it should be.

Later in the day I went to TS to ask if RK had issues with the vendor audit SOP. TS confirmed that RK had sent him notes on things he wanted revised some time ago but that TS had never communicated them to me because he did not agree that the suggested revisions were needed.

DB 11/14/03